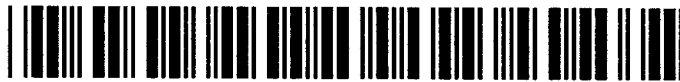


Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Special Nutritionals

ARMS#

12921



0 - FRONT

To: Lori Love@FNSN@FDA.CFSAN
From: <LAL@BF>
Certify: N
Subject: Metabolife
Date: Wednesday, March 18, 1998 at 11:23:25 am EST
Attached: Headers.822

12921

*** Forwarding note from M2B --BFD 03/17/98 09:06 ***
To: LAL --BFD RJM --BFD

From: Margaret Carlson
Subject: Metabolife

Follows is an adverse event report. Please advise.

*** Forwarding note from M2B --BFD 03/17/98 09:01 ***
** Original Mime format message converted for OV by OFSMIME **
From: [REDACTED]
To: M2B@FDACF.SSW.DHHS.GOV
Date: Mon, 16 Mar 1998 16:32:05 -0500
Subject: Metabolife

Original RFC822 Header:

Received: from [REDACTED] by VM.CFSAN.FDA.GOV (IBM VM SMTP V2R2) with TCP;

Mon, 16 Mar 98 16:32:05 EST
Received: from [REDACTED]-Message_Server by [REDACTED]
with Novell GroupWise; Mon, 16 Mar 1998 16:32:45 -0500
Message-Id: <[REDACTED]>
X-Mailer: Novell GroupWise 5.2
Date: Mon, 16 Mar 1998 16:32:05 -0500
From: [REDACTED]
To: M2B@FDACF.SSW.DHHS.GOV
Subject: Metabolife
Mime-Version: 1.0
Content-Type: text/plain; charset=ISO-8859-1
Content-Transfer-Encoding: quoted-printable
Content-Disposition: inline

I have been doing some research on Metabolife and came across the FDA's
proposals for products containing ma huang/ephedrine. I wanted to send you an
e-mail to show my support for this proposal.

On Wednesday, March 11, a friend and co-worker suddenly collapsed at our
office

000001

She was rushed to the hospital where we found that she had a Brain Hemorrhage

The doctors were not sure if she would even make it to get x-rays.

Fortunately

for all of us she did. She underwent emergency surgery for 6 and + hours.

She is currently still in critical condition but is stable. Luckily she was

at work and we were able to get her immediate care otherwise we would have lost her.

Being the person who called 911, I was very concerned about what may have caused this.

At the time of the incident I went through my co-workers desk to find

out if she was taking any medication. I found a bottle of Metabolife in her desk.

I immediately informed the doctor of this not knowing at the time what was

wrong with her. I thought maybe she had just passed out from it. After the doctor

informed us of what happened I, at the time, forgot about the Metabolife

I had found.

The next day I went on the Internet to find out what I could on Brain Hemorrhages

and Aneurysms. I printed this information and read over it carefully.

As I

read the statistics I began to wonder how this could happen to a healthy 36 year-old

woman. The statistics just went there for this to happen to her.

Just

then the Metabolife in her desk came to mind. Could this have helped, I wonder

ed. I began researching everything I could find on this product. I ran across

many disturbing articles about the adverse reactions one on Metabolife's main

ingredients, ma huang, can have, including Cerebral Hemorrhaging. I also read

that this ingredient should not be mixed with caffeine, something my co-worker

did not know. No where on the label or on the product information I found

it say to avoid caffeine when taking Metabolife. My co-worker is a coffee and

Diet Pepsi drinker.

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I am convinced that Metabolife did something if not everything to do with what happened to my co-worker. I know that my co-worker may take other medication including birth control pills and dermatology pills and I have yet to find a study that states the reaction when these pills are mixed with Metabolife. I do not believe enough research has been done on Metabolife for it to be out in the market. I know two other people who are taking this product and I am urging them to stop. One of them reported to me that after she takes her pill and then has a pop she gets light headed and feels drunk the rest of the day. I gave her the articles I have read and I hope she will stop using the product.

I urge the FDA to do some serious investigation into this product. I believe the amount of ma huang is too much for a person to take. My co-worker was a healthy woman with a entire future ahead of her. This almost ended because of this tragedy and I do not want to see it happen to someone else who might not be as lucky as her. I plan on continuing my research into this product. If I can not prove that Metabolife caused this tragedy at least I can make people think twice before using this product. If I can help save someone it will all be worth it. If you have any research that could help me in my continued investigation into this product and ma huang please contact me at [REDACTED] or you may call me at [REDACTED]

I thank you for your time.

Sincerely,

[REDACTED]

000003



DEPARTMENT OF HEALTH AND HUMAN SERVICE

Memorandum

Date October 21, 1998
From Twana R. Chandler, Investigator, HFRCE-750
Subject Follow-up on Adverse Event Report
To CFSAN ARMS Monitor, Bridgette M. Wallace, HFS-636, Rm 5019

On September 29-30, 1998, I called a Ms. [REDACTED] - the consumer- who filed a complaint regarding the product - Metabolife, CFSAN Project # 12921. Ms. [REDACTED] was not in her office. Therefore, I left a message for her to return my calls. I called again on October 1, 1998 and spoke with her about the complaint.

Ms. [REDACTED] told me the name of the co-worker who allegedly became ill from the Metabolite product. She also stated that the co-worker will not be returning to work (due to her illness) for possibly a year and does not wish to discuss the case. Ms. [REDACTED] gave me the name of the co-worker's husband who also works at the same establishment with Ms. [REDACTED]. I have left messages at the husband's place of work requesting him to call me, and attempted to make an appointment to see him, all to no avail. Lastly, I asked Ms. [REDACTED] to call the co-worker and give her my phone number at the FDA office. As of now, I can't get in touch with anyone. Ms. [REDACTED] and the ill co-worker's husband are both always out of the office and do not return my calls.

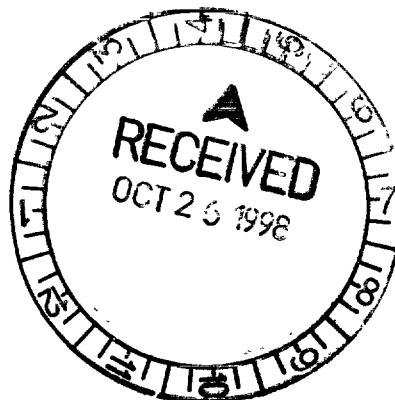
On October 14, 1998, I banyaned you, Ms. Bridgette M. Wallace, explaining the progress of the case and requested guidance. On October 17, 1998, I received a response from you, stating to consider the case closed unless the program office disagrees.

Sincerely,

Twana R. Chandler

Twana R. Chandler

cc: Misc. File



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